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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 30

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/001,039	Applicant(s) JOLLY ET AL.	
	Examiner Robert Schwartzman	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

Status

1)☒ Responsive to communication(s) filed on *03 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5 and 37-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37-56* is/are allowed.

6)☒ Claim(s) *4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *29* .
18)☐ Interview Summary (PTO-413) Paper No(s) _____
19)☐ Notice of Informal Patent Application (PTO-152)
20)☒ Other: *detailed action* .

DETAILED ACTION

This Office action is in response to the amendment filed April 3, 2001. Claims 1-3, 6-11, 57, 58 and 61-68 have been canceled. Claims 4, 5 and 37-56 are pending in this application.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 3, 2001 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite as it recites "title of HT1080 cells" when it should recite "titer on HT1080 cells".

Claim 5 is vague and indefinite as it recites both a titer of 10^6 and a titer of 10^7 in the same claim. Additionally, it recites "title of HT1080 cells" in line 4 when it should recite "titer on HT1080 cells". Furthermore, it recites "titer of HT1080 cells of grater" in line 6 when it should recite "titer on HT1080 cells of greater".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan *et al.* in view of either Mason *et al.* or Takeuchi *et al.* and further in view of Hermann et l. (U.S. Patent No. 5,792,643).

Mulligan *et al.* teaches a retrovirus (MFG) encoding FVIII (column 26, line 27-column 27, line 38). The MFG vector is deleted for gag, pol and env and therefore is replication defective (column 11, lines 29-43). Retroviral particles were prepared using an amphotropic packaging cell line, thus producing retroviruses capable of infecting human cells (column 27, lines 39-44). The B domain deletion of FVIII is a deletion of amino acids 743-1648. This leaves a single B domain SQN tripeptide at amino acids 1649-1651, therefore meeting the definition of an SQN deletion in the present specification (page 26, lines 8-12). Mulligan *et al.* does not teach retroviruses that are resistant to degradation by human complement or retrovirus preparations having a titer on HT1080 cells of greater than 10^6 cfu/ml.

Mason *et al.* teaches retroviruses that are resistant to degradation by human complement due to expression from the retrovirus of a chimeric complement inhibitor protein (column 13, lines 33-48). Takeuchi *et al.* teaches (entire document) retroviruses that are resistant to degradation by human complement due to the fact that they are produced from a human packaging cell line.

Hermann *et al.* teaches methods of preserving recombinant retrovirus preparations such that high titer is retained after storage. Titer is tested on HT1080 cells (column 8, line 54-column 9, line 4). Retrovirus preparations stored in the presence of saccharides were demonstrated to have titers on HT1080 cells of greater than 10^6 cfu/ml (Figures 1-3).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a retroviral vector encoding FVIII as taught by Mulligan *et al.* and to modify the retroviral vector to be resistant to degradation by human complement by the method of Mason *et al.* or Takeuchi *et al.*, motivated by the teaching of Mulligan *et al.* that the retroviral FVIII vector was intended for administration for humans and the teachings of Mason *et al.* and Takeuchi *et al.* that the complement-resistant retrovirus would be more efficient for *in vivo* gene delivery applications. It would further have been obvious to store the retroviral vector in the saccharide containing solutions taught by Hermann *et al.* in which a titer of greater than 10^6 cfu/ml is maintained as Hermann *et al.* teaches that such storage solutions result in greater retention of titer, thus enhancing the ability of one to make and store retrovirus preparations for use in delivering therapeutic genes to patients.

Conclusion

Claims 4 and 5 are rejected. Claims 37-56 are allowed. Claims 5 and 37-56 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Schwartzman whose telephone number is (703) 308-7307. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Schwartz, can be reached at (703) 308-1133. The fax number for this group is (703) 305-3014.

Any inquiry of a administrative or procedural nature or relating to the status of this application or proceeding should be directed to Dianiece Jacobs, Patent Analyst, whose telephone number is (703)-305-3388.

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER

June 2, 2001